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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,354	03/16/2004	Laurence M. Shanley	F-8181	3618
24131	7590	11/14/2007		
LERNER GREENBERG STEMER LLP			EXAMINER	
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			ART UNIT	PAPER NUMBER
			3763	
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			11/14/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/802,354	<b>Applicant(s)</b> SHANLEY, LAURENCE M.	
	<b>Examiner</b> Laura A. Bouchelle	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Appeal brief filed 7/5/07 has been fully considered and subsequently the finality of the previous action has been withdrawn. A new action on the merits follows.

#### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Cherif Cheikh (US 6896670). Cherif Cheikh discloses a safety injection device comprising a protective cap 22, a receiver 14, a needle 22, the protective cap completely encasing the needle and including a seal 24 that covers the opening of the protective cap (Col. 2, lines 63-65), the receiver being movable disposed in the protective cap for movement from a closed position to a functional position where the sharps element projects through a needle guide and from the protective cap.
4. Regarding claims 3, 8, Cherif Cheikh discloses a tab formed on the receiver to correspond with a groove on the protective cover. See Fig. 5.

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5. Regarding claim 6, Cherif Cheikh discloses a membrane seal 24 covering and sealing the opening when the needle is in the retracted position.

6. Regarding claim 9, the syringe has a plunger 30 and a barrel 10.

***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 2, 3, 5, 6, 7, 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherif Cheikh in view of Grabis et al (US 6322540). Claims 2, 5, 7 differ from Cherif Cheikh in calling for the device to comprise a clip ring that limits the movement of the receiver and the cap. Grabis teaches a safe needle device comprising a protective cover 7 and a clip ring 11 that acts as a stop to prevent motion of the receiver past a certain point on the cover. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Cherif Cheikh to have a ring as taught by Grabis to prevent the cover from moving past a certain position on the receiver.

9. Claims 10, 12, 14, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherif Cheikh in view of Grabis as applied to claim 9 above, and further in view of Lee et al (US 5201721). Claims 10, 12 differ from Cherif Cheikh in view of Grabis in calling for the barrel to be formed with a luer lock and the needle and cap to be mounted on the luer lock. Lee teaches a

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safety needle comprising a barrel having a luer lock and a needle and cap mounted on the barrel so that the device can be used with various sized syringe appliances (Col. 5, line 65— Col. 6, line 10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Cherif Cheikh in view of Grabis to have a barrel with a luer lock and a needle and cap mounted on the luer as taught by Lee so that the device can be used with a number of different syringes.

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over lee in view of Cherif Cheikh in view of Grabis as applied to claim 3 above, and further in view of Gregorio (US 5346475). Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cherif Cheikh in view of Grabis in view of Lee in view of Gregorio. Claims 11, 13 differ from the teachings above in calling for the cap to define at least two functional positions. Gregorio teaches a syringe having a cap 28 that is capable of locking in multiple positions such that the needle projects out of the front of the cap by varying amounts to provide varying injection depths. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device above to include a cap capable of locking in more than one functional position as taught by Gregorio so that the needle can project out of the front of the cap by varying amounts.

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***Response to Arguments***


11. Applicant's arguments, see appeal brief, filed 7/5/07, with respect to the rejection of claims 1-15 have been fully considered and are persuasive. The rejection of claims 1-15 has been withdrawn.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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Art Unit 3763

